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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,215	05/17/2001	Peter Huub Gerard Maria Kirchholtes	D/98409 US	7592

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10/02/2002

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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 10/02/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/787,215

Applicant(s)

KIRCHHOLTES ET AL.

Examin r

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE f this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2002 .
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-11 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-11 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This Office Action is a response to Applicant's response filed on July 25 2002 in Paper No. 11 wherein claim 12 is cancelled and claims 1-7, 9-11, and 13-18 have been amended and claims 16-19 are newly submitted. Currently, claims 1-7, 9-11, and 13-18 are pending in this application.

Applicant's amendment filed on July 25 2002 in Paper No. 11 with respect to the rejection of claims 1-5 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expression "highly pure" of record stated in the Office Action dated February 26, 2002 have been fully considered and found persuasive to remove the rejection since the term "highly pure" has been deleted from the claims.

The following is new objection and rejections necessitated by Applicant's amendment filed on July 25 2002 in Paper No. 11.

Claim Objection

Claims 9, 12-15 and 17-18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is well settled that recitation of an inherent property of a composition or method will not further limit claims drawn to a composition or method. In the instant case, for example, the

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shelf life” of the compositions herein in claims 12-15 and 17-18 is an inherent property of the composition herein, which is not considered a limitation of the composition itself.

Moreover, claims 17-18 fail further limited claim 14 since the dependent claims 17-18 are broader in scope than claim 14.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sas et al. (EP 389035 A1) for reasons of record stated in the Office Actions dated February 26, 2002 and July 31, 2001.

Sas et al. discloses a pharmaceutical composition comprising highly pure (7α , 7α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one (tibolone). See abstract and Examples 1-8. Sas et al. also discloses a dosage unit comprising a pharmaceutically suitable solid carrier and the 97.2% pure (7α , 7α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one in an amount of less than 2.50 mg (see Example 6, form I in an amount of 2.5 mg obtained in example 2 having purity 97.2%). Thus, Sas et al. anticipates the claimed invention.

Applicant's remarks filed on July 25 2002 in Paper No. 11 with respect to this rejection of claims 1-3, 7, and 9 made under 35 U.S.C. 102(b) have been fully

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considered and but are not deemed persuasive to remove the rejection as discussed below.

Applicant arguments regarding the two crystal forms, "Form 1" and "Form 2", of (7 α , 7 α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one, are not found convincing, since the instant claims are not limited to any crystal forms of the instant compound.

Again Applicant argues that the presently claimed invention is not anticipated by Sas because the instant composition of (7 α , 7 α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one comprising (7 α , 7 α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one, the impurity, in an amount less than 0.5%, 0.25%, or 0.1% by weight whereas Sas is silent about the presence of any impurities in the composition. However, as discussed in the previous Office Action (February 26, 2002) the expression "less than 0.5%, 0.25%, or 0.1% by weight" in the instant claims is seen to merely limit the claims to any amount less than 0.5%, 0.25%, or 0.1% by weight including 0%. Thus, the composition of Sas comprising 0% by weight of impurity herein is within the instant claim. Therefore, the instant invention is seen to be anticipated by Sas.

Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sas et al. and Van Vliet et al. for reasons of record stated in the Office Actions dated February 26, 2002 and July 31, 2001.

Applicant's remarks filed on July 25 2002 in Paper No. 11 with respect to this rejection of claims 4-6 made under 35 U.S.C. 103(a) have been fully considered and but are not deemed persuasive to remove the rejection for the following reasons.

Applicants' argument that Sas does not teach or suggest that the instant impurity is present in an amount less than 0.5% by weight is not found convincing. As discussed above or in the previous Office Action, the expression "less than 0.5% by weight" in the instant claims is seen to merely limit the claims to any amount less than 0.5% by weight. Thus, the instant claims clearly read on the teachings of Sas.

Van Vliet et al. has been cited by the examiner primarily for its teaching that the instant impurity, (7 α , 7 α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one is known to be present (i.e., less than 1%) in the final product of (7 α , 7 α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one due to the last step of synthesis under weakly acidic conditions. Thus, as discussed in the previous Office Actions, one having ordinary skill (e.g., a synthetic organic chemist) would have found it obvious to further purify the desired product to remove the impurity in the desired amount because the

method of purification herein is considered a **conventional** to a skilled artisan, involving merely routine skill in the art.

For the above stated reasons, the claimed invention is clearly obvious in view of the prior art. Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-11 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sas et al. (EP 389035 A1) for reasons of record stated in the Office Actions dated February 26, 2002 and July 31, 2001.

Applicant's remarks filed on July 25 2002 in Paper No. 11 with respect to this rejection of claims 10-18 made under 35 U.S.C. 103(a) have been fully considered and but are not deemed persuasive to remove the rejection. As discussed in the previous Office Actions, the shelf lives herein of the compositions are expected since they are the inherent property of the composition.

Further, the employment of aging crystal in a method of crystallization for purify the desired product herein is **well known** and **conventional** to a skilled artisan, involving merely routine skill in the art.

As discussed in the previous Office Action, Applicant's examples 1-6 in the specification at pages 6-9 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive. Applicant's remarks regarding the comparison with prior art are not found persuasive since the results herein, e.g. the self lives, are clearly expected and not unexpected based on the cited prior art, i.e., the method in Sas has provided a much better stability of the instant compound, e.g., the shelf-life, even under changing storage conditions is notably improved (see Sas page 2 lines 39-40). Therefore, the results on the preparation of the compositions herein and their storage time are expected as taught and suggested by the cited prior art herein. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

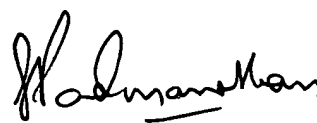
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
September 16, 2002


SREENI PADMANABHAN
PRIMARY EXAMINER

9/30/02